JUL 26 2001

K012191

510(k) Summary for TERATECH Model 2000 Handheld Ultrasound System with Doppler and Harmonic Imaging Modes

1. SPONSOR

Teratech Corporation
77-79 Terrace Hall Rd.
Burlington, MA 01803

Contact Person: Charles F. Hottinger, Ph.D., RAC,
Regulatory Affairs Consultant

Telephone: 408-741-1006

Date Prepared: July 2, 2001

2. DEVICE NAME

Proprietary Name:	TERATECH Model 2000 Handheld Ultrasound System with Doppler and Harmonic Imaging Modes
Common/Usual Name:	Ultrasound System and Transducers
Classification Name:	Ultrasonic Pulsed Doppler Imaging System (21 CFR 892.1550, 90 IYN) Ultrasonic Pulsed Echo Imaging System (21 CFR 892.1560, 90 IYO) Diagnostic Ultrasound Transducer (21 CFR 892.1570, 90-ITX)

3. PREDICATE DEVICES

Acuson Sequoia™ Ultrasound System and Harmonic Imaging (K97367)
Acuson Aspen™ Ultrasound System (K991805)

4. INTENDED USE

The TERATECH Model 2000 Handheld Ultrasound System with Doppler and Harmonic Imaging Modes is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body; specific indications for use a tabulated in Section 4.3 of this submission.

5. DEVICE DESCRIPTION

Technical specifications for the Model 2000 Handheld Ultrasound System with Doppler and Harmonic Imaging Modes are as follows:

System

Transducer frequencies:	2-4 MHz (4C2 and 4V2), 4-8 MHz (8EC4, 8L4)
Frame rate:	15 - 58 fps (Imaging only)
Ultrasound lines/frame:	128
Fields of View:	2.5 - 24 cm
External Video Output:	Composite Video, VGA Monitor
Liquid-Crystal Display:	15.7" SXGA TFT
Size: Width:	13.125"
Height:	11.25"
Depth:	1.62"
Weight: Laptop Computer	8.6 lb.
Smart Probe	10 oz

Electrical

External Power:	Input: 115-250 VAC, Output: 19 VDC @ 4A
Battery:	Li-Ion battery pack (70 Whr)
Leakage Current:	50 μA maximum
Primary Breakdown Voltage:	greater than 1500 V AC
Safety Standards:	IEC 601-1, UL 2601, Can/CSA C22.2 601.1
Protection Class:	Class I: per IEC 601-1
Degree of Protection:	Type BF: per IEC 601-1

Environmental

Mechanical Shock (Smart Probe): IEC 68-2-27 compliant (Smart Probe only)

Mechanical Vibration:	Sinusoidal: IEC 68-2-6 (Smart Probe only)
Drop Test (to concrete):	3 feet
Operating Temperature:	0 to 50 C (Smart Probe only)
Humidity:	20 to 80% RH, non-condensing
Water Resistance:	Transducer array watertight to the strain relief
Altitude:	0 – 12,500 feet (operating)

Refer to computer manufacturer's documentation for relevant environmental specifications.

Storage

Temperature:	-25 to 60 C
Humidity:	15 to 98% RH, non-condensing

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The TERATECH Model 2000 Handheld Ultrasound System with Doppler and Harmonic Imaging Modes is substantially equivalent to the Acuson Sequoia™ and Aspen™, which are currently in commercial distribution in the United States, since the subject device has intended uses and modes of operation which are a subset of those of the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 2001

TERATECH Corporation
% Mr. Mark Job
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K012191
Trade Name: Teratech Model 2000 Handheld Ultrasound System with Doppler and Harmonic Imaging Modes
Regulatory Class: II/21 CFR 892.1550
Product Code: 90 IYN
Regulatory Class: II/21 CFR 892.1560
Product Code: 90 IYO
Dated: July 12, 2001
Received: July 13, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Teratech Model 2000 Handheld Ultrasound System as described in your premarket notification:

Transducer Model Number

4C2
4V2
8EC4
8L4

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA)

may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ____Teratech Model 2000 System with Doppler and Harmonic Imaging Modes_____
Transducer: (see comments)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler[a]	Combined Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P[1]	N	N		N	N	N
	Abdominal	P[1]	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P[1]	N	N		N	N	N
	Small Organ (Thyroid, Breast, Testes, etc.)	N	N	N		N	N	N
	Neonatal Cephalic	P[1]	N	N		N	N	N
	Adult Cephalic	P[1]	N	N		N	N	N
	Trans-rectal	P[2]	N	N		N	N	N
	Trans-vaginal	P[2]	N	N		N	N	N
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N	N	N		N	N	N
	Musculo-skel. (Superficial)	N	N	N		N	N	N
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P[1]	N	N		N	N	N
	Cardiac Pediatric	P[1]	N	N		N	N	N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P[1]	N	N		N	N	N
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD, and (non-directional) Power Doppler.
[b]B+M; B+PWD; B+CD; B+DPD; B+PD.
[c]Harmonic Imaging (HI)
Additional Comments: P[1]: uses previously cleared under K992505 with 3 MHz Model L3 (Linear) Transducer (including use in military field settings in addition to hospital/clinic settings):
P[2]: uses previously cleared under K010883 with Model 8EC4.
N: subject of this submission.
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ____Teratech 2000 System with Doppler and Harmonic Imaging Modes___
Transducer: _4C2_
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler[a]	Combined Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P[1]	N	N		N	N	N
	Abdominal	P[1]	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P[1]	N	N		N	N	N
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD, and (non-directional) Power Doppler.
[b]B+M; B+PWD; B+CD; B+DPD; B+PD.
[c]Harmonic Imaging (HI)
Additional Comments: P[1]: uses previously cleared under K992505 with 3 MHz Model L3 (Linear) Transducer (including use in military field settings in addition to hospital/clinic settings):
N: subject of this submission.
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Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ____Teratech Model 2000 System with Doppler and Harmonic Imaging Modes_____
Transducer: _4V2_
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler[a]	Combined Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P[1]	N	N		N	N	N
	Abdominal	P[1]	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P[1]	N	N		N	N	N
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	P[1]	N	N		N	N	N
	Adult Cephalic	P[1]	N	N		N	N	N
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P[1]	N	N		N	N	N
	Cardiac Pediatric	P[1]	N	N		N	N	N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD, and (non-directional) Power Doppler.
[b]B+M; B+PWD; B+CD; B+DPD; B+PD.
[c]Harmonic Imaging (HI)
Additional Comments: P[1]: uses previously cleared under K992505 with 3 MHz Model L3 (Linear) Transducer (including use in military field settings in addition to hospital/clinic settings):
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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ____Teratech Model 2000 System with Doppler and Harmonic Imaging Modes____
Transducer: _8EC4_
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler[a]	Combined Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P[2]	N	N		N	N	N
	Trans-vaginal	P[2]	N	N		N	N	N
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD, and (non-directional) Power Doppler.
[b]B+M; B+PWD; B+CD; B+DPD; B+PD.
[c]Harmonic Imaging (HI)
Additional Comments: P[1]: uses previously cleared under K992505 with 3 MHz Model L3 (Linear) Transducer (including use in military field settings in addition to hospital/clinic settings):
P[2]: uses previously cleared under K010883 with Model 8EC4.
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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012191

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ____Teratech Model *f*2000 System with Doppler and Harmonic Imaging Modes_____
Transducer: _8L4_
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler[a]	Combined Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P[1]	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P[1]	N	N		N	N	N
	Small Organ (Thyroid, Breast, Testes, etc.)	N	N	N		N	N	N
	Neonatal Cephalic	P[1]	N	N		N	N	N
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N	N	N		N	N	N
	Musculo-skel. (Superficial)	N	N	N		N	N	N
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P[1]	N	N		N	N	N
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD, and (non-directional) Power Doppler.
[b]B+M; B+PWD; B+CD; B+DPD; B+PD.
[c]Harmonic Imaging (HI)
Additional Comments: P[1]: uses previously cleared under K992505 with 3 MHz Model L3 (Linear) Transducer (including use in military field settings in addition to hospital/clinic settings):
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